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NORTH AMERICAN INSULATION MANUFACTURERS ASSOCIATION

VIA E-MAIL AND OVERNIGHT MAIL

May 26, 2010

Ruth M. Lunn, Ph.D.
Director, Report on Carcinogens Group
National Toxicology Program
National Institute of Environmental Health Sciences
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RE: Mitchell and Moorman Studies – Correction and Clarification

Dear Dr. Lunn:

I serve as Chairman of the Health and Safety Advisory Subcommittee for the North American Insulation Manufacturers Association ("NAIMA"). As I mentioned in our recent meeting in your office, I have been studying glass fiber health effects for over 20 years and have co-authored a number of papers on fiber toxicology.

NAIMA has asked me to submit the following information as soon as possible to provide correction and clarification to the Mitchell and Moorman studies cited in the "Draft Report on Carcinogens Substance Profile for Glass Wool Fibers (Respirable) as a Class" ("Draft Substance Profile"). As described in more detail below, one critical factor to consider is that there was no actual exposure to insulation glass fibers in those studies.

We have located the lengthy original final study report ("Final Report") on which are based the two publications cited in the Draft Substance Profile. That Final Report provides critical corrective and clarifying data.

The Draft Substance Profile states on page 3: "Inhalation exposure of F344 rats to two types of Owens-Corning glass wool (4 to 6 μm in diameter and > 20 μm long or 0.5 to 3.5 μm in diameter and > 10 μm long) significantly increased the incidence of mononuclear- cell leukemia in rats (males and females combined); as with the findings for Tempstran code 100/475 glass fibers in this strain (discussed above), these findings were considered to be exposure-related (Mitchell *et al.* 1986, Moorman *et al.* 1988)." We are not sure where the idea came from that these rats were

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exposed to two types of glass wool. It is not supported in either of the published studies or the study report.[1]

The two published papers cited are based on a 317-page Final Study Report (and its 541 pages of appendices) entitled, *A Chronic Inhalation Toxicology Study in Monkeys and Rats Exposed to Fibrous Glass*, which was conducted for NIOSH at the Battelle Columbus Laboratories. The Final Report of the study was submitted to NIOSH on October 25, 1982. (Project number G-7188, Contract number 210-78-0037).

The full Report enclosed herewith contains information that establishes clearly the following:

1. There was only one Owens Corning glass insulation wool fiber tested.

2. The second Owens Corning fiber tested was not a glass wool fiber but an Owens Corning manufactured special purpose glass fiber that was used as an air filter media.

3. The 4–12 micron average diameter of the one insulation wool tested contained few, if any, rat respirable fibers.

4. The lung burden of fibers in the insulation wool exposed animals was the same as the lung burden in the control animals.

5. The Final Report does not attribute the mononuclear cell leukemia findings to the tested fibers. Rather, the Final Report states on page 291: "The reason for the increased incidence of mononuclear cell leukemia in test groups as compared to the control group in this study is not apparent. The possibility of an exposure related increase in incidence of this neoplasm cannot be ruled out." (emphasis added).

FIBERS TESTED

Page 26 of the Final Report states the following:

> Four Commercial Products were selected for evaluation as follows:
>
> (1) FG Insulation Fiberglass*, 4 to 12 micrometer diameter fiber with 4.5 percent binder (red – urea and phenol formaldehyde)
> (2) FM Series Air Filter Media*, 1 micrometer diameter fiber with 12.5 percent binder (yellow – phenol formaldehyde)

[1] Neither the 1986 Mitchell article nor the 1988 Moorman article describes more than one of the test fibers as being an insulation fiber. Mitchell only describes the fibers by referencing their dimensions identifying them as "4-6 micron glass fiber > 20 micron long with red binder" and 0.5 – 3.5 micron glass fiber > 10 micron long with yellow binder." Moorman identifies the glass fibers used in exposure groups 1 and 2 stating ". . . FG Insulation Fiberglass and FM Series Air Filter Media (Owens-Corning Fiberglass Corp. Newark, Ohio) were used for treatments 1 and 2 respectively and contained phenol-formaldehyde binder."

(3) FM Series Air Filter Media*, 1 micrometer diameter fiber without binder
(4) Tempstran Code 100/475**, 1 micrometer diameter fiber without binder.

* Owens-Corning Fiberglas Corporation, Newark, Ohio 43657
** Manville Corporation, Denver, Colorado 80217

Based on grinding and classification tests, the red FG Insulation Fiberglas and yellow FM Series Air Filter Media were selected for making the two fiber fractions with binder, and the Tempstran Code 100/475 glass fiber was selected for the two fractions with the diameter < 3.5 micrometer fibers [with lengths] > 10 micrometers and < 10 micrometers long.

The FM series air "Filter Media," was a special purpose fiber previously made by flame attenuation by Owens Corning at its Santa Clara, California plant (product literature attached hereto). The Owens Corning Filter Media, like the Tempstran Code 100/475, was used only in high efficiency filtration applications. As stated in the Final Report, it had a nominal diameter of 1 micron.

RESPIRABILITITY OF THE INSULATION WOOL FIBERS TESTED

It is well accepted that to be respirable in the rat, glass fibers must have diameters of 1-2 microns or less. For example, the IARC 2002 Monograph (No. 81) on Man Made Vitreous Fibers states on page 246: "For rats and hamsters, alveolar deposition is essentially zero when the aerodynamic diameter of the fibres exceeds 3.5 microns and the aspect ratio is > 10." This corresponds to a fiber diameter of 1.5 microns or less (Fig. 9, p. 243, IARC 2002).

The fiber size distribution of the glass wool insulation sample is given in Table 19 of the Final Report and is attached hereto. It is clear that little, if any, of the aerosol was even respirable in the rat.

THERE WAS NO DIFFERENCE IN FIBER BURDEN BETWEEN THE INSULATION GLASS WOOL EXPOSED ANIMALS AND THE CONTROLS

Given that the insulation fiber aerosol would not be considered respirable in the rodent, the lung burden data are critical in determining whether there was any actual exposure.

In appendix J of the Final Report is the following: "Table J 13 is a summary of the calculated lung burden for both monkeys and rats and the average number of particles found in a gram of dried lung tissue. The number of fibers found in the control animals (FO5) group was subtracted from each exposure group. Approximately the same number of fibers were found in the control animals as those exposed to the large diameter fibrous glass (FO1 the insulation glass wool fibers)." Table J-13 is attached hereto.

In summary, the Final Report provides factual details further supporting that only one, and not two, insulation wool fiber was tested. The aerosol for the one insulation wool fiber tested was effectively non-respirable as evidenced by its fiber size distribution given above and the fact that the fiber burden in the lungs of the "exposed" animals was the same as in the non-exposed controls.

If there is no dose, there was no actual exposure of insulation glass fibers and there can be no exposure-related effect. Thus, the FO1 group was effectively a second control group for the study. When considered this way, the study has no significant findings for any of the tested fibers.

The investigators found a slightly significant elevation of mononuclear cell leukemia but only when males and females were combined. Any observed effect simply cannot be exposure-related if there was not actual exposure. Indeed, the Final Report recognizes this and states on page 291: "The mononuclear cell leukemia was statistically significant when each test group was individually compared to the control group. This neoplasm is commonly seen in aged Fischer 344 rats. The incidence of mononuclear cell leukemia occurring in these control rats is essentially the same as that observed in control Fischer rats from 24-month studies over the past several years at Battelle's Columbus Laboratories. The reason for the increased incidence of mononuclear cell leukemia in test groups as compared to the control group in this study is not apparent. The possibility of an exposure related increase in incidence of this neoplasm cannot be ruled out." This last sentence seems merely a recitation of the rule that one cannot prove the negative and hardly constitutes sufficient evidence of cancer in this animal study.

NAIMA appreciates the NTP's consideration of this additional information and requests that it be made part of the public record that the Board of Scientific Counselors will review.

[Redacted]

John G. Hadley, Ph.D.
Chairman
Health and Safety Advisory Subcommittee

Enclosures

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